DEPARTMENT OF MANAGED HEALTH CARE CALIFORNIA HMO HELP CENTER DIVISION OF PLAN SURVEYS

FOLLOW-UP SURVEY REPORT
NON-ROUTINE MEDICAL SURVEY

OF
BLUE SHIELD OF CALIFORNIA

A FULL SERVICE HEALTH PLAN

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Follow-Up Survey Report of a Non-Routine Medical Survey Blue Shield of California A Full Service Health Plan

TABLE OF CONTENTS

EXECUTIVE SUMMARY	1
SECTION I: SUMMARY STATUS OF DEFICIENCIES	4
SECTION II: DISCUSSION OF DEFICIENCIES	5
SECTION III: DISCUSSION OF RECOMMENDATIONS	14
SECTION IV: SURVEY CONCLUSION	15
APPENDICES:	
A. APPLICABLE STATUTES AND REGULATIONS	16
B. SURVEY METHODOLOGY	18

EXECUTIVE SUMMARY

Introduction

Pursuant to Section 1341(a) of the Knox-Keene Act (Knox-Keene or the Act), the Department of Managed Health Care (the "Department") is charged with executing the laws of California relating to health care service plans and the health care service plan business. Those laws include, but are not limited to, laws that ensure health care service plans provide enrollees with access to quality health care services and protect and promote the interests of the enrollees.

The Department's Division of Plan Surveys conducts medical surveys as a vehicle to ensure that health plans meet certain obligations to enrollees under the Act¹.

Background Leading to This Non-Routine Survey

The Department conducted a routine² survey of Blue Shield of California (the "Plan") in January 2006. As a result of a survey finding, the failure to perform timely review of member-initiated quality of care complaints, the Department voiced concern and placed the Plan "on notice" regarding this issue.

The Plan acknowledged the concern and agreed to begin corrective actions immediately. However, in close proximity to the January survey finding, an anonymous Plan employee ("Whistleblower") contacted the Department and reported serious breaches in the Plan's processing of quality of care case reviews.

The Whistleblower provided the Department with a list of cases dating back to 2004, alleging the Plan's failure to investigate and process member-initiated complaints. Coupled with information derived from members' quality of care complaints filed with the Department's HMO Help Center, the Department had a basis of good cause to conduct a non-routine³ medical survey of the Plan. The Director authorized review of the Plan's peer review operations under Section 1370 of the Act. When a medical review has been authorized, the survey team is required by law to ensure the confidentiality of the records and information reviewed, along with the peer review proceedings.

¹ References made throughout this report to "Section" are to sections of the Knox-Keene Health Care Service Plan Act of 1975, as amended [California Health and Safety Code Section 1340 *et seq.* (the Act)]. References to "Rule" are to the regulations promulgated pursuant to the Act [Title 28 of the California Code of Regulations].

² The Department is required to conduct "routine" medical surveys of licensed managed health care service plans at least every three years. The survey reviews plan operations in relation to access to care, quality improvement, grievances and appeals, and utilization management. [Section 1380]

³ An examination or survey is additional or non-routine for good cause for the purposes of Section 1382(b) when the plan has violated, or the Director has reason to believe that the plan has violated, any of the provisions of Section 1370. [Rule 1300.82.1(a)(2)]

Non-Routine Survey

The Department conducted a non-routine survey at the Plan's offices in El Dorado Hills, California, from June 28 through June 30, 2006, and on July 19, 2006. Through interviews, file reviews and examination of case logs, the non-routine survey assessed the adequacy of the Plan's process for evaluating and resolving quality of care complaints filed by Plan enrollees.

Following the June/July on-site visits, the Department issued a Preliminary Survey Report identifying deficiencies related to the Plan's processing and review of member-initiated quality of care complaints, including:

- 1. The Plan's failure to establish procedures in accordance with Department regulations for continuously reviewing member-initiated quality of care complaints, and failure to demonstrate that the Plan's process for conducting review of quality of care concerns was reasonable.
- 2. The Plan's failure to demonstrate that the Quality Program relating to member-initiated quality of care concerns was directed by providers, that care provided was reviewed, problems identified and effective action taken with planned follow-up.
- 3. The Plan's failure to provide a quality assurance program designed to ensure that member-initiated quality of care problems are identified and corrected for all provider entities.
- 4. A significant gap in the Plan's Quality Improvement Program requirements to provide for a reasonable methodology for on-going monitoring of member-initiated quality of care complaints.
- 5. A deficiency in associating the review of member-initiated quality of care complaints within the full scope of Quality Improvement activities and providing an effective relationship to the Plan's administrative structures.

On October 11, 2006, the Plan submitted its corrective action plan in response to the Department's survey report. On December 19, 2006, based on a review of the Plan's response, the Department published its final compliance determinations in the Final Report. http://www.dmhc.ca.gov/library/reports/med_survey/surveys/043full010407.pdf

Interim Activities (From Final Non-Routine Report to Follow-Up Visit⁴)

The Department monitored the Plan's improvement efforts to ensure resolution of the backlog of 900 plus cases and also the implementation of a new process that effectively addressed member-initiated quality of care complaints going forward. The interim activities required of the Plan between December 2006 and May 2007 included:

⁴ Final Non-Routine Survey Report published on December 19, 2006 Follow-up Survey conducted May/June 2007

- Submission of monthly updates to the Department describing the development and implementation of the member-initiated quality of care complaint process, including policies, staffing, training and committee review.
- Status reports and inventories of the Plan's serious backlog (900 plus cases) of member-initiated quality of care complaints;

Purpose of Follow-Up Survey and Report

The Follow-Up Survey was conducted from May 21, 2007, through June 8, 2007, at the Plan's offices in El Dorado Hills, California. The purpose of the Follow-Up Survey was to confirm the correction of outstanding deficiencies reported in the Final Report. If deficiencies remain uncorrected, a Plan is subject to potential disciplinary actions pursuant to Health and Safety Code 1380(i)(l).

Summary of Follow-Up Survey Results

At the time of the June 2006 non-routine survey, the Department was unable to complete a review of the Plan's entire quality review process because case review in the Grievance and Appeal Department was backlogged. Some cases had been waiting for a physician review for a year or more. The Department expected immediate Plan attention to this problem and complete processing and resolution of all backlogged cases.

The Follow-Up Survey found that the Plan had completed the review and handling of its backlog of 993 member-initiated complaints; however, the Department remains concerned at the length of time the Plan took to appropriately process and resolve these cases. Some cases were filed with the Plan a year prior to the non-routine survey (2005) and full resolution of the 993 cases was not complete until February 2007.

The Plan corrected Deficiencies #1, 3, and 4:

These deficiencies referred to the Plan's failure to:

- 1) Establish procedures to ensure continuous review of quality of care complaints,
- 3) Identify quality of care problems for all provider entities,
- 4) Demonstrate a methodology for on-going monitoring of quality of care complaints, and

Deficiency #2 was not corrected:

The Plan's process, involving both backlogged cases and new cases, did not demonstrate consistency in assigning, implementing and tracking corrective actions to resolve quality of care problems, nor follow-up to confirm resolution.

Deficiency #5 was not corrected:

This deficiency cites issues in the review of member-initiated quality of care complaints within the full scope of Quality Improvement activities and providing an effective relationship to the Plan's administrative structures.

A copy of this report has been referred to the Department's Office of Enforcement.

SECTION I: SUMMARY STATUS OF DEFICIENCIES

Table 1 below summarizes the compliance status for survey deficiencies identified in the December 19, 2006 Final Non-Routine Survey Report.⁵

TABLE 1

SUMMARY OF JUNE 2006 NON-ROUTINE SURVEY DEFICIENCIES			
#	DEFICIENCY STATEMENT [Section or Rule]	Follow-up Visit 5/21/07-6/8/07	
1	The Plan failed to establish procedures in accordance with Department regulations for continuously reviewing quality of care, performance of medical personnel, utilization of services and facilities, and costs when processing member-initiated quality of care issues. The Plan also failed to demonstrate the reasonableness of procedures and adequacy of the implementation thereof. [Section 1370 and Rule 1300.70(c)]	Corrected	
2	The Plan failed to demonstrate that the quality assurance program is directed by providers and that care provided is being reviewed; that problems are being identified; that effective action is taken to improve care where deficiencies are identified; and that follow-up is planned where indicated when handling member-initiated quality of care issues. [Rule 1300.70(a)(1)]	Not Corrected	
3	The Plan failed to provide a quality assurance program designed to ensure member-initiated quality of care problems are identified and corrected for all provider entities. Failings included: Failure to provide administrative and clinical staff support with sufficient knowledge and experience to assist in carrying out their assigned quality assurance activities. Failure to ensure that a level of care that meets professionally recognized standards of practice is being delivered to all enrollees. [Rule 1300.70(b)(2)(F), Rule 1300.70(b)(1)(A)(B)(C)]	Corrected	

⁵ Non-Routine Survey performed on June 28 through June 30, 2006, and July 19, 2006

4	The Plan is deficient in demonstrating Quality Improvement Program requirements in relation to member-initiated quality of care review, including: The methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity [Rule 1300.70(b)(2)(A)]	Corrected
5	The Department's assessment of the Plan's member-initiated quality assurance program demonstrates a deficiency in associating the review of quality of care with: The scope of quality assurance activities within the organization The structure of the program itself and its relationship to the Plan's administrative structure The operation of the quality assurance program; and the level of activity of the program and its effectiveness in identifying and correcting deficiencies in care [Rule 1300.70(a)(4)(A)(B)(C)(D)]	Not Corrected

SECTION II: DISCUSSION OF DEFICIENCIES

Deficiency #1: The Plan failed to establish procedures in accordance with

> Department regulations for continuously reviewing quality of care, performance of medical personnel, utilization of services and facilities, and costs when processing member-initiated quality of care issues. The Plan also failed to demonstrate the reasonableness of procedures

and adequacy of the implementation thereof.

[Section 1370 and Rule 1300.70(c)]

Outstanding Issues at the Time of the Final Report

In late June 2006 in association with the non-routine survey, the Plan initiated a Potential Quality Issue Redesign Project to ensure member-initiated quality of care issues were investigated timely by appropriate Plan staff and review committees. The redesign would include organizational changes, policy and procedure changes, and hiring of additional review staff. The completion of the project was projected for 2007.

The Department directed the Plan to submit monthly updates showing progress on the Potential Quality Issue Redesign Project, as well as documents such as process maps, policies and procedures, and revised closing letters to monitor the Plan's progress toward:

- 1) Resolving its backlog, and
- 2) Redesigning its system to more effectively and expeditiously address current and future member-initiated complaints.

Conditions at Time of Follow-Up Survey

The Department found that the Plan's Potential Quality Issue Redesign Project has been substantially implemented. Policies have been developed. Key organizational changes have been implemented (e.g., Peer Review Committee's first meeting took place in August 2006) and workflows revised.

STATUS: CORRECTED

The Department finds that the Plan has developed policies and procedures for the review of member-initiated quality of care issues and has demonstrated that it has substantially implemented these policies and procedures.

Deficiency #2:

The Plan failed to demonstrate that the quality assurance program is directed by providers and that care provided is being reviewed; that problems are being identified; that effective action is taken to improve care where deficiencies are identified; and that follow-up is planned where indicated when handling member-initiated quality of care issues. [Rule 1300.70(a)(1)]

Outstanding Issues at the Time of the Final Report

Rule 1300.70(a)(1) requires compliance with four elements, ensuring:

- The Plan identifies quality of care problems
- The Plan conducts review of quality concerns,
- The Providers direct and are involved in that review, and
- The Plan takes effective corrective action to address those problems with planned follow-up. 6

Because the June 2006 non-routine survey identified a serious backlog of cases waiting to undergo an appropriate quality review, the Department could not evaluate the operation of the entire quality review process. During the Follow-Up Survey, the Department verified the processing and resolution of the case backlog, including the integrity of the quality review and implementation of a process to timely review and resolve new complaints. The Department's findings are divided into an evaluation of the quality review of the backlog and a separate review of the handling of new cases.

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⁶ Such action includes developing appropriate corrective action plans and conducting follow-up to ensure implementation and effectiveness. The specific level and type of corrective action should vary depending upon the problems found and should correspond with the severity level assigned. Corrective actions may include, for example, education, restriction of privileges, and systems changes.

Follow-up Report of a Non-Routine Medical Survey Blue Shield of California A Full-Service Health Plan July 8, 2008

Conditions at Time of Follow-Up Survey: Backlogged Cases

During the Follow-Up Survey, the Department reviewed a sample of 37 backlogged cases and Plan tracking reports showing resolution of all backlogged cases. Ninety-nine percent of the case review was completed by the end of 2006, with full completion by mid-February 2007.

The Department confirmed all backlogged cases had been reviewed by a clinical professional. The Department, however, found case examples in which all quality issues had not been identified and cases that should have been reported to higher physician executive review due to the seriousness of the issue or implications of system-wide problems.⁷

The Department reviewed a subset of 23 backlogged cases where quality of care problems had been identified by the Plan.⁸ In this subset, the Department found examples in which the Plan failed to assign, implement, and/or follow-up on corrective action plans.⁹

⁷ The Department has granted confidential treatment of specific case summaries and results of peer review activities. Cases #3, #8, #26.

⁸ Some cases referred for quality review do not warrant corrective actions because they have been appropriately reviewed and found to have no quality of care problems. Also, in any cases where problems existed but the Plan failed to identify the problems, corrective actions would not have occurred although they were warranted—resulting in a missed opportunity to improve care.

⁹ The Department has granted confidential treatment of specific case summaries and results of peer review activities. Cases # 24, #21, #26, # 41, # 49.

Table 2 summarizes results of the Department's audit at the time of the Follow-Up Survey.

TABLE 2 BACKLOGGED MEMBER-INITIATED COMPLAINTS: POTENTIAL QUALITY OF CARE ISSUES

FILE TYPE	# OF FILES REVIEWED	ELEMENT	# COMPLIANT	# DEFICIENT
	27	Overall timeliness of handling	0	37
Potential		Reviewed by a quality management clinical professional	37	0
quality issues		Reviewed at the appropriate level	30	7
complaints receipt		All significant quality problems identified	31	6
date: 1/1/04 - 6/30/06	37	If a quality problem was confirmed (23 of the 37 cases), corrective actions were appropriately handled	11 (N/A for 14 cases with no problems identified)	12
		Overall appropriateness of handling (except timeliness, which was 100% deficient)	17	20

Conditions at Time of Follow-Up Survey: Case Review for New Quality of Care Cases

The Department found that all post-redesign cases were reviewed by a clinical professional. Post-redesign reviews began with the quality management nurse review, severity level assignment, case summary review by Medical Director and/or full case review referral to the Medical Director. All case files scored as severity level II and III following the Medical Director review were reviewed by the Peer Review Committee. In its review of post-redesign cases, the Department found that escalation of cases had improved from the backlog period. In 35 of the 36 post-redesign cases, the review was escalated to the appropriate level of clinical expertise/peer review.

Case review of new cases showed improved problem identification when compared to cases from the backlog. In 34 of the 36 cases, all significant quality problems were identified.

Beginning February 2007, the responsibility for assigning corrective action plans to cases in which a quality of care problem was identified, requiring additional follow-up, was given to the Plan's Credentialing Committee. In two of the post-redesign cases, the Plan did not assign a corrective action plan when the seriousness of the quality of care issue(s) warranted intervention.¹⁰

Tracking and follow-up of corrective action plans by the Credentialing Committee has not been fully implemented under the new process. It is unclear what process/database the Plan will utilize to monitor ongoing corrective actions and to assess their

¹⁰ The Department has granted confidential treatment of specific case summaries and results of peer review activities. Case summary #132.

effectiveness. The ability to report practitioner-specific potential quality issues remains a manual process linked to orange stickers physically placed on the cover of the credentialing file.

The Plan's peer review process may conclude that corrective action is necessary to adequately address the problem. The Plan may delegate this responsibility to the medical group/ IPA who oversees the physician at issue. This delegation places the responsibility on the medical group/ IPA to select and implement appropriate corrective action to resolve the problem.

However, the Plan has not developed a formal process for conducting its own independent investigation to verify that medical group/ IPA corrective actions are appropriate, implemented and completed, or that the actions resolved the problem.

Table 3 summarizes the results of the Department's audit of post-redesign cases.

TABLE 3
POST-REDESIGN FILE AUDIT RESULTS AT TIME OF FOLLOW-UP SURVEY

FILE TYPE	# OF FILES REVIEWED	ELEMENT	# COMPLIANT	# DEFICIENT
Member-initiated	36	Overall timeliness of handling	34	2
complaints referred for review of potential quality issues Post- redesign complaint receipt date: 9/15/06- 3/31/06		Reviewed by a quality management clinical professional	36	0
		Reviewed at the appropriate level	35	1
		All significant quality problems identified	34	2
		If a quality problem was confirmed (14 of the 36 cases), corrective actions were appropriately handled:	10	4
		Overall appropriateness of handling	28	8

STATUS: NOT CORRECTED

The process of assigning, implementing and tracking correction of quality of care problems, either as assigned by the Credentialing Committee or in deference to the actions developed by Medical Groups/ IPAs, remains problematic. More than half of the backlogged cases in the survey sample indicated a problem in the handling of corrective actions.

The Plan has not developed a formal process for conducting its own independent investigation to verify that medical group/ IPA assigned corrective actions are appropriate, implemented and completed, and that corrective actions resolved the problem. These important steps: 1) assigning effective corrective action to improve care, when indicated, and 2) follow-up on these actions, continues to be an area of Department concern for the Plan's quality of care review process.

Follow-up Report of a Non-Routine Medical Survey Blue Shield of California A Full-Service Health Plan July 8, 2008

Pursuant to Title 28 California Code of Regulations (CCR), Rule 1300.80.10¹¹, the Department requires the Plan to respond within 30 days as to the current status of the corrective actions and/or measures taken by the Plan to resolve the deficiency.

The Department will continue to monitor the status of this deficiency by reviewing the sufficiency of the Plan's corrective action and by conducting periodic unannounced on-site reviews to validate the Plan's corrective actions. The Plan is directed to demonstrate complete correction of the remaining deficiency within three months.

Deficiency #3:

The Plan failed to provide a quality assurance program designed to ensure member-initiated quality of care problems are identified and corrected for all provider entities. Failures include:

- Failure to provide administrative and clinical staff support with sufficient knowledge and experience to assist in carrying out their assigned quality assurance activities
- Failure to ensure that a level of care that meets professionally recognized standards of practice is being delivered to all enrollees [Rule 1300.70(b)(2)(F), Rule 1300.70(b)(1)(A)(B)(C)]

Outstanding Issues at the Time of the Final Report

The process to screen and identify potential quality of care problems arising from member complaints was identified as an issue during the 2006 routine medical survey. The survey team observed that the volume of quality issues appeared low when compared to the size of the Plan's membership and service areas. Since initial "in-take" of complaints flows through Customer Service, the team questioned whether the screening criteria were adequate to identify and capture quality of care problems voiced by members.

A possible solution was to re-evaluate the complaint screening criteria, revise the criteria in order to capture quality of care problems and conduct training for Customer Service staff. At the time of the June 2006 non-routine survey, the Plan was still considering Department feedback.

The Plan's organizational structure bifurcated the processing of member-initiated quality of care complaints between the Grievance and Appeal Department and the Health Care Services Department. The survey team found the Plan did not complete the review of member-initiated quality of care cases because of a failure to ensure timely hand-off between the Grievance and Appeal nurses and the medical staff. By the completion of the 2007 non-routine Follow-Up

Where such deficiencies may be reasonably adjudged to require long-term corrective action or to be of a nature which may be reasonably expected to require a period longer than 30 days to remedy, in some instances evidence that the plan has initiated remedial action and is on the way to achieving acceptable levels of compliance may be submitted."

¹¹ Title 28 California Code of Regulations, Rule 1300.80.10 provides: "Prior to or immediately upon the expiration of the 30-day period following notice to a plan of a deficiency as provided in subdivision (h) of Section 1380 of the Act, the plan shall file a written statement with the Director identifying the deficiency and describing the action taken to correct the deficiency and the results of such action. The report shall be signed by a principal officer of the plan.

Follow-up Report of a Non-Routine Medical Survey Blue Shield of California A Full-Service Health Plan July 8, 2008

Survey, the Plan had revised workflows for customer service staff, and a tool for tracking each step of the potential quality issue process.

Conditions at Time of Follow-Up Survey

In relation to the Plan's ability to identify and capture quality of care complaints filed by members, the Plan had made progress towards training customer service staff to improve screening and capture of quality complaints. The primary training tool was an e-course that educated staff on how to identify potential quality issues as they handle member-generated complaints, and how to refer those cases for clinical review. The Department reviewed the e-course during the Follow-Up Survey and found it to be a well-designed tool, which includes both training and testing functions.

The e-course was not piloted until December 2006 (more than five months after the Department's Non-Routine Survey on-site visit) and general training did not begin until February 2007 (over seven months after the on-site visit).

When the Department performed this Follow-Up Survey, nearly one year later, a significant portion of the staff (20%) had not been trained. The Plan projected a completion date of June 2007 for all staff completing the training e-course.

The roll-out of staff training correlated with an increase in the volume of potential quality issues identified by customer service representatives:

- 50 additional quality issues per month on average in 2006
- 107 additional quality issues per month on average at the end of Quarter 1, 2007
- 139 additional quality issues per month on average at the end of Quarter 2, 2007

The Plan estimates that a total of 400 potential quality issues per month might be handled when the process improvements to capture quality issues are fully implemented plan-wide. This represents a potential 800% increase over 2006 numbers.

The slow progression in training staff, led to a gradual increase of incoming quality of care complaints, and in turn, to a slow hiring process. The Plan's quality management nurse staff increased to from 1 to 3.8 full-time employees. Appeals and Grievance coordinator staffing remained stable at five full-time employees. Given the current volume of cases, this level of staffing has allowed the Plan to complete registered nurse level review in a timely manner. Increased staffing may be necessary when all customer service representatives are trained and the referral volume stabilizes.

STATUS: CORRECTED

The Department takes note and questions the length of time the Plan has taken to act and improve the process to identify and capture member initiated quality concerns. Delays in implementing changes to better identify and address concerns arising from member complaints is inconsistent with the objectives of the Act.

The Department will follow the Plan's progress to complete staff training, further improving its ability to identify potential quality issues. The Department cautions the Plan in limiting or creating barriers to the capture, acknowledgment and resolution of quality of care complaints arising from its membership due to its measured training and hiring progression.

Deficiency #4:

The Plan is deficient in demonstrating Quality Improvement Program requirements in relation to member-initiated quality of care review, including:

• The methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity. [Rule 1300.70(b)(2)(A)]

Outstanding Issues at the Time of the Final Report

The Plan delivered an analysis of member-initiated quality concerns to the Quality Management Committee and the Board on October 24, 2006, and November 9, 2006.

Because the timeliness of the quality review had been identified as a very serious problem, the Plan had established a 90-day turnaround time for processing member-initiated quality complaints from receipt to closure. The 90-day standard had been adopted but not applied in operations at the conclusion of the non-routine survey.

To monitor the Plan's progress, the Department directed the Plan to submit quality complaint processing policies and procedures, reports on backlogged cases and monthly Potential Quality Issue Inventory Tracking Reports which showed the dates of new incoming cases.

Conditions at Time of Follow-Up Survey

File review of backlogged cases demonstrated a serious delay in processing quality of care cases which has been cited and reported in the Final Report. However, for new cases processed through the Plan's revised case review processes, the Plan consistently met the 90-day standard and appears to follow the newly revised processing policies and procedures ensuring an appropriate quality review.

STATUS: CORRECTED

The Department finds that the Plan has completed its review of the backlogged cases and instituted a revised quality review process to monitor quality issues raised by Plan members. The Department finds that the Plan has demonstrated compliance with the 90-day processing standard for the review of member-initiated quality of care complaints and has sufficient mechanisms in place to monitor to this standard.

Deficiency #5:

The Department's assessment of a Plan's member-initiated quality assurance program demonstrates a deficiency in associating the review of quality of care with:

- The scope of quality assurance activities within the organization
- The structure of the program itself and its relationship to the Plan's administrative structure
- The operation of the quality assurance program
- The level of activity of the program and its effectiveness in identifying and correcting deficiencies in care [Rule 1300.70.(a)(4)(A)(B)(C)(D)]

Outstanding Issues at the Time of the Final Report

At the conclusion of the 2006 onsite non-routine survey, the Plan had yet to identify a single "owner" taking responsibility for the "end-to-end" process of identifying, reviewing, resolving and monitoring member-initiated quality of care complaints. The Plan had not formally recognized member-generated quality complaints as an important component of the overall quality program or its value as a mechanism to improve problems in care delivery.

To monitor the Plan's progress, the Department directed the Plan to submit monthly updates to ensure implementation of corrective actions, specifically relating to the handling of these complaints within a revised organizational structure. The Plan was also directed to submit its Service Level Agreements describing the requirements for the Customer Service and Appeals and Grievance Departments in hand-offs between the Departments, as well as the actions that will be taken when Service Level Agreements are not met.

Conditions at Time of Follow-Up Survey

The Plan revised the organizational structure and assigned responsibility to the Medical Director for Quality Improvement as the owner for member-initiated quality of care complaints. The Plan demonstrated implementation of staffing, and service-level agreements with the Customer Service and the Appeals and Grievance Departments to ensure timely processing and hand-offs between Departments. The Department found that the agreements have been signed, implemented and they stipulate the actions to be taken in the event of partner non-compliance.

Although the Plan revised its organizational structure and assigned responsibility to the Medical Director for Quality Improvement to ensure proper and timely handling and clinical review of member-initiated quality of care complaints, the Department must continue to monitor the process to ensure the handling of quality of care complaints has successfully transitioned and is consistently handled within the Plan's operations and quality program.

Following the completion of the follow-up survey, the Department received additional information from inside and outside the plan from current and former staff members which suggested that the processing of member initiated quality of care complaints remains problematic. Information reported to the Department raised questions as to whether appropriate numbers of clinical staff have been hired to review PQI complaints as well the Plan's decision to make frequent changes to the review procedures which creates the potential for inconsistency in case review.

Based on this information, the Department sent a letter of inquiry to the Plan on April 16, 2008 requesting the Plan's response to these concerns. The Department received the Plan's response on April 30, 2008 and will continue to follow-up with the Plan and evaluate any new concerns.

STATUS: NOT CORRECTED

In citing to this deficiency, there was no further action required by Blue Shield, other than the continued dedication to ensure the integrity and success of the newly revamped member-initiated PQI process. The Department will continue to monitor the status of the Plan's quality of care review program, the associated reported issues and confirm Plan compliance by conducting the 2009 routine survey and if needed, periodic unannounced on-site reviews to validate the Plan's corrective actions. The Department will provide additional direction and clarification regarding the notice and scope of the unscheduled onsite PQI reviews at the appropriate time. The Department will continue to monitor the Plan until it has demonstrated complete correction of this remaining deficiency.

SECTION III: DISCUSSION OF RECOMMENDATIONS

In accordance with section 1380(g) of the Act, Department analysts offer advice and assistance to the Plan in the form of survey recommendations. Survey recommendations are intended to alert the Plan to weaknesses in its operations that have the potential to become deficiencies in the future. Plan executive staff has been apprised of these issues and the possible negative impact on public safety and/or the services rendered to enrollees. The Plan should review and evaluate recommendations and take action as appropriate.

- 1. Develop procedures for assessing, reviewing, and overseeing corrective action plans instituted by provider groups and facilities
- 2. Develop tracking systems to support timely implementation and follow-up of corrective actions. An automated tracking system will also facilitate reporting on individual providers, as well as reporting and analysis of trends by provider, quality issue, severity, etc.
- 3. Develop reports to track the implementation of corrective actions, to track and confirm completion of a corrective action extending over time, and to assess the effectiveness of the corrective action plan (e.g., by tracking recurrences).
- 4. Design policy and require documentation of the rationale for every severity level assignment and include in each peer review file. The peer review exercise should avoid restating the case summary and stating conclusions. Require clear rationale or basis linking the facts to the peer review conclusion.

SECTION IV: SURVEY CONCLUSION

During this Follow-Up Survey, the Department found that the Plan has corrected three of the five deficiencies that were outstanding from the 2006 Non-Routine Survey on member-initiated complaints which require review for potential quality of care concerns.

The Plan reported the status of the corrective actions and/or measures taken by the Plan to resolve Deficiency #2. The Department will continue to monitor the Plan until it has demonstrated complete correction of these remaining deficiencies.

A P P E N D I X A

A. APPLICABLE STATUTES AND REGULATIONS

The following are the specific citations used in this report in identifying the deficiencies.

Section 1370

Every plan shall establish procedures in accordance with department regulations for continuously reviewing the quality of care, performance, or medical personnel, utilization of services and facilities, and costs. Notwithstanding any other provision of law, there shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any person who participates in plan or provider quality of care or utilization reviews by peer review committees which are composed chiefly of physicians and surgeons or dentists, psychologists, or optometrists, or any of the above, for any act performed during the reviews if the person acts without malice, has made a reasonable effort to obtain the facts of the matter, and believes that the action taken is warranted by the facts, and neither the proceedings nor the records of the reviews shall be subject to discovery, nor shall any person in attendance at the reviews be required to testify as to what transpired thereat. Disclosure of the proceedings or records to the governing body of a plan or to any person or entity designated by the plan to review activities of the plan or provider committees shall not alter the status of the records or of the proceedings as privileged communications.

Rule 1300.70(c)

In addition to the internal quality of care review system, a plan shall design and implement reasonable procedures for continuously reviewing the performance of health care personnel, and the utilization of services and facilities, and cost. The reasonableness of the procedures and the adequacy of the implementation thereof shall be demonstrated to the Department.

Rule 1300.70(a)(1)

The Quality Assurance program must be directed by providers and must document that the quality of care provided is being reviewed, that problems are being identified, that effective action is taken to improve care where deficiencies are identified, and that follow-up is planned where indicated.

Rule 1300.70(b)(2)(F)

There must be administrative and clinical staff support with sufficient knowledge and experience to assist in carrying out their assigned QA activities for the plan and delegated entities.

Rule 1300.70(b)(1)(A)(B)(C)

To meet the requirements of the Act which require plans to continuously review the quality of care provided, each plan's quality assurance program shall be designed to ensure that: A level of care which meets professionally recognized standards of practice is being delivered to all enrollees, quality of care problems are identified and corrected for all provider entities, and physicians (or in the case of specialized plans, dentists, optometrists, psychologists or other appropriate licensed professionals) who provide care to the plan's enrollees are an integral part of the Quality Assurance program.

Rule 1300.70(b)(2)(A)

There must be a written Quality Assurance plan describing the goals and objectives of the program and organization arrangements, including staffing, the methodology for on-going monitoring and evaluation of health services, the scope of the program, and required levels of activity.

Rule 1300.70(a)(4)(A)(B)(C)(D)

The Department's assessment of a plan's Quality Assurance program will focus on the scope of Quality Assurance activities within the organization, the structure of the program and its relationship to the plan's administrative structure, the operation of the Quality Assurance program, and the level of activity of the program and its effectiveness in identifying and correcting deficiencies in care.

A P P E N D I X B

B. SURVEY METHODOLOGY

Overview of Follow-Up Survey Methodology

The Department assessed the current status of the deficiencies found during the non-routine survey through:

- 1. interviews with Plan management and staff;
- 2. review of policies, reports, committee minutes, work plans and other documents; and
- 3. audits of member case files for 37 backlogged cases and 36 member-generated complaints received following the redesign of the Plan's systems (post-redesign cases).

The survey team included staff from the Department's Division of Plan Surveys and Office of Enforcement, as well as clinical consultants from the Department's contractor, Managed Healthcare Unlimited, Inc.

The Department evaluated the Health Plan's Quality Management processes subject to the Act by:

- 1. Conducting interviews;
- 2. Examining Plan documents; and
- 3. Reviewing case files for member-generated complaints.

1. Interviews

The Plan's legal counsel observed while the Department conducted extensive interviews with Plan staff regarding the handling of backlogged cases and the development and implementation of a redesigned process for handling member-initiated quality of care concerns. Informal discussions also occurred during the case file review to clarify Plan documents and processes, especially when inconsistencies were identified between actual procedures and written policies.

2. Document Review

The Department reviewed policies and procedures, work plans and other documents to assess the handling of the backlogged cases and the appropriateness of handling membergenerated quality of care complaints post-redesign. The survey team also reviewed reports that the Plan uses to monitor quality of care and examined committee meeting minutes to determine (a) whether identification, investigation, and resolution of quality of care concerns were appropriate and timely; and (b) whether quality of care issues were reported to the appropriate level relative to the seriousness of the quality issue.

3. Case File Review

The Department reviewed Plan files for 73 member-generated quality of care complaints. Because the Plan's processes evolved markedly following the Department's Non-Routine Survey in June and July 2006, the Department selected a sample of 37 backlogged cases and a separate sample of 36 member-generated complaints received following the redesign of the Plan's systems (post-redesign cases). This allowed the Department to

separately assess the handling of backlogged cases vs. the effectiveness of the new processes. Case review was conducted using a standardized file review tool that collected descriptive data such as:

- 1. Communications between the Plan and the enrollee (and/or his/her representatives) whether written, by telephone, e-mail or FAX;
- 2. Communications between the Plan and the involved provider(s) whether written, by telephone, e-mail or FAX;
- 3. Documents related to the enrollee's complaint/grievance, including telephone log information;
- 4. Relevant medical records;
- 5. Documentation of the Plan's review of the relevant medical records;
- 6. Peer review documentation, including the Peer Review determination and rationale;
- 7. Documentation of corrective actions:
- 8. Minutes of meetings of any committee that reviewed the case; and,
- 9. Other pieces of evidence of the Plan's investigation, and resolution of the issue(s).

The Department reviewed the cases using a standardized file review worksheet. The worksheet also assessed the Plan's performance on key standards related to quality review and oversight. These key performance standards included:

- 1. Whether the case was appropriately identified and referred to the Quality Management Department.
- 2. Whether the case was reviewed by a quality management clinician (registered nurse or medical director).
- 3. Whether the case was examined/reviewed at the appropriate level (i.e., registered nurse, medical director, committee,).
- 4. If a problem was confirmed whether:
 - a) corrective actions were recommended.
 - b) corrective actions were appropriate to the issue.
 - c) corrective actions were initiated and completed.
 - d) follow-up was conducted.
- 5. Whether the case was reviewed in a timely manner.
- 6. Whether results were communicated to the appropriate level committees/personnel.

7. Whether, overall, the case was handled appropriately.

The Department used experienced surveyors/reviewers to perform the case file reviews, including physicians with extensive clinical experience, managed care administration experience, and experience performing utilization management and quality management review for the Department's routine and non-routine medical surveys; registered nurses with critical care nursing, managed care and regulatory survey experience; and a research analyst to provide quality management and analytical expertise.

Each file was reviewed by two surveyors. If the case revealed significant quality management process findings, a third surveyor reviewed the case to validate the first two surveyors' concerns. Review results were compiled in a common database. The case was counted in the numerator of quality management deficient files only if each reviewer independently found a concern.

PLANS APPENDED STATEMENT

The Plan has appended its response to this Report as authorized under section 1382(d) of the Act. To view that appended plan response, please access the link below:

Follow-Up Survey Report Dated: July 18, 2008
Supplemental Plan Statement [Health & Safety Code § 1382(d)]